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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional) TPIP039

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Kristin Miele
Signature

Kristin Miele
Type or Printed Name

Application Number:	Filed:
10/820,382	4/8/2004

First Name Inventor: Matthew Peterson

Art Unit: 1625	Examiner: Celia C. Chang

Applicant requests review of the final rejection in the above-entitled application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated of the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☑ attorney or agent of record. Registration Number 53,852

☐ attorney or agent under 37 CFR 1.34(a).
Registration number if acting under 37 CFR 1.34(a)_____

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May 4, 2006
Date

Paul Burgess
Signature

(781) 674-7816
Telephone Number

Paul Burgess
Typed or printed name

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☑ Total of 1 form is submitted.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Matthew Peterson et al.		
Serial No.:	10/820,382	Group No.:	1625
Filed:	04/08/2004	Examiner:	Celia C. Chang
For:	GABAPENTIN COMPOSITIONS		
Attorney Docket Number:	TPIP039		

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Dear Sir:

This invention relates to novel and unknown crystalline salts of gabapentin. In the first Office Action, the Examiner rejected the pending claims as obvious in view of one reference disclosing known gabapentin hydrochloride and a couple of other references disclosing multiple acid/base pair possibilities useful in pharmaceuticals, but not specific to gabapentin. Applicants' subsequent response included arguments refuting both the motivation to combine and the reasonable expectation of success of novel gabapentin salt formation given the cited references. Examiner's second and final Office Action maintained the same rejections without further analysis or apparent consideration of Applicants' arguments. Applicants filed an after-final response with a recently published article which demonstrates the current unpredictability of salt formation. Applicants received an Advisory Action in which the Examiner apparently gave no weight to the recently published article.

Applicants are requesting a pre-appeal brief conference because the Examiner has not considered the persuasive reference which Applicants have submitted and believe overcomes the

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Kristin Miele
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obviousness rejection. The recently published article describes the unpredictability of salt formation for any one particular drug and one particular acid/base pair (April 8, 2006 Response, last paragraph of page 9). The Examiner did not discuss this dispositive reference in her subsequent Advisory Action and incorrectly stated that "No factual evidence supports unexpectancy was made in the record." In fact, the reference specifically states that "...there exists no a priori prediction procedure to determine the feasibility of salt formation in a given acid-base pair." This statement alone should support the patentability of Applicants' novel gabapentin salts.

Applicants' other non-obviousness arguments are:

1) The references cited by the Examiner simply state gabapentin can exist as a hydrochloride salt and that other known drugs can form salts with other acid/base pairs. These references do not make obvious particular salts of gabapentin. This argument is also refuted by Applicants' cited reference describing the unpredictability of salt formation.

2) The references cited by the Examiner fail to teach or suggest how to create the particular salts identified by Applicants. Example 1 of Applicants' application discloses a very specific method for the formation of the novel gabapentin DL-tartaric acid salt with a particular novel PXRD pattern. This pattern is compared to the previously known forms of gabapentin and is shown to be different. The Examiner's references do not suggest the method described in Example 1 or in the other examples.

3) Examiner's contention that "the physical property of a compound is the innate nature of that product" (See April 28, 2005 Office Action, last paragraph of page 3) is not a proper obviousness analysis. None of the salts claimed are the innate nature of any of the references the Examiner has cited. The novel salts identified in Applicants' application are not the innate result of the known gabapentin hydrochloride disclosed in Augart et al. or in any other reference relied upon by Examiner.

4) It is not obvious that the resultant novel salts would be crystalline. The physical state of the salt (i.e., amorphous or crystalline), the particular physical structure, and the properties associated with a particular structure cannot be predicted. Just as the recently published article confirms the unpredictability of salt formation, it is equally unpredictable that the resultant novel

salt would be crystalline. As such, each of the claimed novel crystalline salts represents an unexpected result.

Applicants believe the Examiner has not properly considered its arguments, and more importantly, has not considered the recently published persuasive article. Accordingly, Applicants respectfully request withdrawal of the obviousness rejections.

Respectfully submitted,

May 4, 2006, 2006

By: _____

Paul Burgess, Patent Attorney
Reg. No. 53,852

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